



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT OPERATION

RECEIVED

APR 08 2003

TECH CENTER 1800/2900

In re Application of:

**Chih-Ming Chen; Joseph Chou and
Unchalee Kositprapa**

Serial No.: 09/763,831

Group Art Unit: 3745

Filed: July 11, 2001

Examiner: Susan T. Tran

For: **OMEPRAZOLE FORMULATION**

RECEIVED

APR 03 2003

TECHNOLOGY CENTER R3700

New York, NY 10036
March 24, 2003

Commissioner of Patents & Trademarks
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

The following statement of relevance is submitted with the accompanying
Form PTO/SB/08A.

Document
Designation

AA
U.S.P. 4,045,563

Relevance

Relates to a substituted 2-[pyridylalkylenesulfinyl]-ben-
zimidazoles with gastric acid secretion inhibiting effects.

AB
U.S.P. 4,045,564

Relates to benzimidazole derivatives useful as gastric acid
secretion inhibitors.

AC
U.S.P. 4,182,766

Relates to naph[2,3-d]imidazoles.

I hereby certify that this correspondence is
being deposited with the United States Postal
Service as first class mail in an envelope
addressed to:

Commissioner of Patents
Washington, D.C. 20231

on March 24, 2003

Shari Jackson

Shari Jackson

04/02/2003 MAHMED1 00000087 09763831

02 FC:1806

180.00 OP

| <u>Document Designation</u> | <u>Relevance</u> |
|-----------------------------|---|
| AD U.S.P. 4,255,431 | Relates to a gastric acid secretion inhibiting substituted 2-(2-benzimidazolyl)-pyridines, pharmaceutical preparations containing same, and method for inhibiting gastric acid secretion. |
| AE U.S.P. 4,337,257 | Relates to gastric acid secretion inhibiting substituted 2-(2-benzimidazolyl)-pyridines, their preparations containing same, and method for inhibiting gastric acid secretion. |
| AF U.S.P. 4,359,465 | Relates to methods for treating gastrointestinal inflammation. |
| AG U.S.P. 4,432,966 | Relates to compressed tablets for disintegration in the colon comprising an active ingredient containing nucleus coated with a first layer containing microcrystalline cellulose which is coated with an enteric organic polymer coating. |
| AH U.S.P. 4,508,905 | Relates to substituted 2-(benzimidazolyl) pyridines. |
| AI U.S.P. 4,544,750 | Relates to certain pyridyl-N-oxide intermediates for the preparation of omeprazole. |
| AJ U.S.P. 4,620,008 | Relates to processes for the preparation of omeprazole and intermediates therefore. |
| AK U.S.P. 4,636,499 | Relates to sulphenamides. |
| AL U.S.P. 4,686,230 | Relates to a picoline derivatives useful as gastric acid secretion inhibitors. |
| AM U.S.P. 4,738,974 | Relates to base addition salts of omeprazole. |
| AN U.S.P. 4,786,505 | Relates to a new pharmaceutical preparation for oral use containing omeprazole. |
| AO U.S.P. 4,840,799 | Relates to a process for preparing rapidly disintegrating particles. |
| AP U.S.P. 4,853,230 | Relates to pharmaceutical formulations of acid labile substances for oral use. |
| AQ U.S.P. 5,045,321 | Relates to a stabilized pharmaceutical composition and its production. |

| | |
|------------------------|--|
| AR U.S.P. 5,093,132 | Relates to a stabilized pharmaceutical composition and its production. |
| AS U.S.P. 5,093,342 | Relates to the use of omeprazole as an antimicrobial agent. |
| AT U.S.P. 5,178,867 | Relates to a dosage form for delivering drug in short time period. |
| AU U.S.P. 5,204,118 | Relates to pharmaceutical compositions and methods for treating the symptoms of indulgence. |
| AV U.S.P. 5,244,670 | Relates to an ingestible pharmaceutical composition for treating upper gastrointestinal tract distress. |
| AW U.S.P. 5,288,506 | Relates to antacid compositions with prolonged gastric residence time. |
| AX U.S.P. 5,304,540 | Relates to pharmaceutical compositions and methods for using the same. |
| AY U.S.P. 5,330,982 | Relates to a pharmaceutical composition containing a 5 HT receptor antagonist and a method of treating gastrointestinal disorders therewith. |
| AZ U.S.P. 5,352,688 | Relates to a method for the treatment of bradyphrenia in Parkinson's disease. |
| BA U.S.P. 5,362,424 | Relates to a microencapsulation for controlled oral drug delivery system. |
| BB U.S.P. 5,385,739 | Relates to stable compositions of gastroprotected omeprazole microgranules and process for the production thereof. |
| BC U.S.P. 5,389,664 | Relates to alleviating stomach ulcers in swine. |
| BD U.S.P. 5,399,700 | Relates to method for preparing enteric coated oral drugs containing acid unstable compounds. |
| BE U.S.P. 5,417,980 | Relates to pharmaceutical compositions and methods for treating the symptoms of overindulgence. |
| BF U.S.P. 5,433,959 | Relates to a stabilized pharmaceutical composition. |
| BG U.S.P. 5,508,041 | Relates to microencapsulation for controlled oral drug delivery system. |

| | |
|------------------------|--|
| BH U.S.P. 5,518,730 | Relates to a biodegradable controlled release flash flow melt spun delivery system. |
| BI U.S.P. 5,599,794 | Relates to a synergistic combination of a substance with gastric acid secretion inhibiting effect and an acid degradable antibiotic. |
| BJ U.S.P. 5,620,964 | Relates to compositions for treating and inhibiting gastric and duodenal ulcers. |
| BK U.S.P. 5,622,717 | Relates to ulcer prevention using a melt spun hydrogel. |
| BL U.S.P. 5,637,320 | Relates to a controlled absorption naproxen formulation for once-daily administration. |
| BM U.S.P. 5,639,478 | Relates to a method to stabilize a pharmaceutical composition and its production. |
| BN U.S.P. 5,693,818 | Relates to a process for preparing pure salts of pyridinylmethyl-sulfinyl-1h-benzimidazole. |
| BO U.S.P. 5,753,265 | Relates to a multiple unit pharmaceutical preparation. |
| CA WO 85/03436 | Relates to diffusion coated multiple units dosage form. |
| CB WO 95/01783 | Relates to a new pharmaceutical formulation. |
| CC WO 95/10264 | Relates to a tablet containing enteric granules. |
| CD WO 95/12590 | Relates to a preparation of omeprazole and lansoprazole and intermediates useful therein. |
| CE WO 96/01612 | Relates to a novel drug delivery system. |
| CF WO 96/01622 | Relates to a new oral pharmaceutical formulation containing magnesium salt of omeprazole. |
| CG WO 96/01623 | Relates to multiple unit tableted dosage form. |
| CH WO 96/24375 | Relates to a new pharmaceutical dosage form. |

| | |
|--------------------|--|
| CI WO 96/02535 | Relates to a process for synthesis of substituted sulfoxides. |
| CJ CA 1,127,158 | Relates to 2-pyridymethylsulfinyl-benzimidazole compounds. |
| CK CA 1,129,417 | Relates to gastric acid secretion inhibiting substituted 2-(2-benzimidazolyl)-pyridines, their preparation, pharmaceutical preparations containing same, and method for inhibiting gastric acid secretion. |
| CL CA 1,234,118 | Relates to pyridyl-n-oxide intermediates for the preparation of omeprazole. |
| CM CA 1,263,119 | Relates to production of 2-(2 pyridylmethylsulfinyl) benzimidazole compounds. |
| CN CA 1,264,751 | Relates to base addition salts of omeprazole. |
| CO CA 1,292,693 | Relates to a pharmaceutical preparation containing omeprazole. |
| CP CA 1,302,891 | Relates to pharmaceutical formulations of acid labile substances for oral use. |
| CQ CA 1,324,758 | Relates to transdermal antisecretory agents for gastrointestinal disease. |
| CR CA 1,338,377 | Relates to stabilized pharmaceutical composition and its production. |
| CS CA 2,037,101 | Relates to omeprazole compositions designed for administration in rectum. |
| CT CA 2,046,364 | Relates to galenic process for omeprazole containing pellets. |
| CU CA 2,083,605 | Relates to method for synthesis. |
| CV CA 2,139,653 | Relates to optically pure salts of pyrinylmethyl sulfinyl-1H-benzimidazole compounds. |
| CW CA 2,140,347 | Relates to injection and injection kit containing omeprazole and it analogs. |
| CX CA 2,166,483 | Relates to a new pharmaceutical formulation. |

| | |
|---|---|
| CY CA 2,166,794 | Relates to magnesium omeprazole. |
| CZ CA 2,170,647 | Relates to multiple unit tableted dosage form. |
| DA CA 2,193,681 | Relates to a new oral pharmaceutical containing magnesium salt of omeprazole. |
| DB GB 1,234,058 | Relates to pyridylalkyloxy and pyridyalkythioazole derivatives. |
| DC EPO 124,495 | Relates to omeprazole salts. |
| EA L. Olbe, S.E. et al., Present Situation and Future Prospects of Medical Treatment., <u>Gastrins and the Vagus</u> , Academic Press p. 245-250, 1979. | Relates to omeprazole. |
| EB Ekenved et al. "Studies with H 168/68, a Novel Gastric Acid Secretion Inhibitor., <u>Gut</u> , Vol. 22, No. 10, October 1981 p. A877. | Relates to omeprazole. |
| EC Erik Fellenius et al., Substituted Benzimidazoles Inhibit Gastric Acid Secretion by Blocking (H ⁺ + K ⁺) ATPase., <u>Nature</u> , Vol. 290, March 12, 1981 p. 159-161 | Relates to omeprazole. |
| ED Tore Lind, et al., Effect of Omeprazole – A Gastric Proton Pump Inhibitor on Pentagastrin Stimulated Acid Secretion in Man., <u>Gut</u> , Vol. 24 p. 270-276, 1983. | Relates to omeprazole. |
| EE K-Fr Sewin et al., Effect of Substituted Benzimidazoles on Acid Secretion in Isolated and Enriched Guinea Pig Parietal Cells., <u>Gut</u> , Vol. 24 p. 557-560, June 1983. | Relates to omeprazole. |

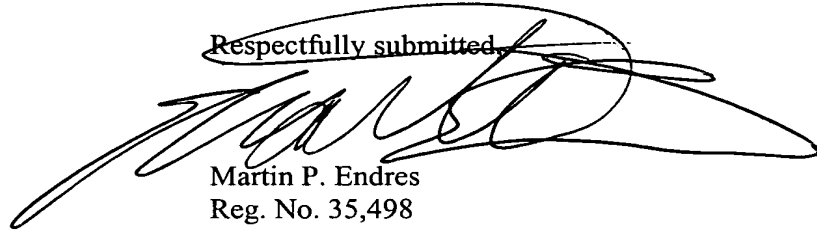
- EF
Haken Larsson et al., Inhibition of Gastric Acid Secretion by Omeprazole in the Dog and the Rat. Gastroenterology, Vol. 85 p. 900-907, October 1983. Relates to omeprazole.
- EG
Walter Londong et al. Dose-Response Study of Omeprazole on Meal-Stimulated Gastric Acid Secretion and Gastrin Release., Gastroenterology, Vol. 85 p. 1373-1378, December 1983. Relates to omeprazole.
- EH
Stanislaw J. et al., Effects of Omeprazole, a Substituted Benzimidazole, on Gastrointestinal Secretions, Serum Gastrin and Gastric Mucosal Blood Flow on Dogs. Gastroenterology, Vol. 86, p. 71-77, January 1984. Relates to omeprazole.
- EI
D.A. Henry et al., Omeprazole: Effects on Oxidative Drug Metabolism., British Journal of Clinical Pharmacology, Vol. 18, p. 195-200, August 1984. Relates to omeprazole.
- EJ
B.K. Sharma et al., Optimal Dose of Oral Omeprazole for Maximal 24 Hour Decrease of Intragastric Acidity. Gut, Vol. 25 p. 957-964, September 1984. Relates to omeprazole.
- EK
H.P.M. Festen et al., Effect of Oral Omeprazole on Serum Gastrin and Serum Pepsinogen I Levels. Gastroenterology, Vol 87 p. 1030-1034, November 1984. Relates to omeprazole.
- EL
Peter Prichard et al. Omeprazole: A Study of Its Inhibition of Gastric pH and Oral Pharmacokinetics After Morning or Evening Dosages Gastroenterology, Vol. 88 pp. 64-69 January 1985. Relates to omeprazole.

| | |
|--|---|
| EM | Relates to omeprazole. |
| K.O. Borg and L. Olbe, Omeprazole – A Survey of Preclinical Data, <u>Gastroenterology</u> , p. 15-22, 37-51, 71-77, 79-93, 105-120, June 1985. | |
| EN | Relates to omeprazole. |
| 50 th Edition of Physician's, 1996 Desk Reference p. 529—531. | |
| EO | Relates to omeprazole. |
| K.O. Borg, L. Olbe Proceedings of the First International Symposium on Omeprazole, Supplement to the <u>Scandinavian Journal of Gastroenterology</u> , pp. 11-17, 31-38, 54-56, 59-60, 75-76, 77-78, 89-91, 92-98, 99-104, 105-135, 179, 182-183, 187-195, 1996. | |
| FA | Relates to omeprazole formulations. |
| U.S.P. 6,096,340 | |
| FB | Relates to a new pharmaceutical formulation and process. |
| WO 96/24338 | |
| FC | Relates to an oral pharmaceutical preparation comprising an antiulcer activity compound, and process for its production. |
| EP 1010423 A2 | |
| FD | Relates to omeprazole formulation. |
| September 23, 1994 Decision of the Korean Patent Office Regarding Korean Patent No. 55426 with Certified English Translation See page 4, line 13 to page 5, line 8. | |
| FE | Relates to omeprazole formulation. |
| Korean Patent Application 92-17571 with Certified English Translation | |

Full text copies or abstracts of the above-identified reference were previously supplied in application Serial No. 09/143,167 with the exception of reference FA-FE. Pursuant to 37 C.F.R. 1.98 (d) copies of references AA-EO are not provided with this Information Disclosure Statement because copies of these references were supplied in the parent application, Serial No. 09/143,167. If additional copies are needed, the Examiner is invited to telephone the undersigned and copies will be immediately provided.

Copies of references FA-FE are enclosed. It is respectfully requested that this art be considered by the Examiner in the above-entitled application and made of record therein. Because the first and non-final Office Action has been issued in this matter, a check in the amount of \$180.00 is enclosed pursuant to 37 C.F.R. §1.97(c)(2). If any additional fee is due, the Commissioner is hereby authorized to charge Deposit Account No. 08-1540.

Respectfully submitted,

A large, stylized handwritten signature in black ink, appearing to read 'Martin P. Endres', is written over the 'Respectfully submitted,' text.

Martin P. Endres
Reg. No. 35,498

MAILING ADDRESS:
HEDMAN & COSTIGAN, P.C.
1185 Avenue of the Americas
New York, NY 10036
(212) 302-8989